PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
701586-52521		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US03/08743	25 March 2003 (25.03.2003)	25 March 2002 (25.03.2002)
International Patent Classification (IPC) or national classification and IPC		
IPC(7): A61K 31/70; C12N 15/63; C07H 21/04 and US Cl.: 514/44; 435/320.1, 455; 536/23.2, 23.4, 23.7		
Applicant		
THE TRUSTEES OF BOSTON UNIVERSITY		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

 ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of ___ sheets.

3. This report contains indications relating to the following items:

 - I ☒ Basis of the report
 - II ☐ Priority
 - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23 October 2003 (23.10.2003)	28 July 2004 (28.07.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer Quang Nguyen, Ph.D. Telephone No. (703) 308-2801

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International appli[redacted]No.
PCT/US03/08743

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed.

☒ the description:
pages 1-79 as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☒ the claims:
pages 80-84 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☒ the drawings:
pages 1-10 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☒ the sequence listing part of the description:
pages 1-3 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☒ furnished subsequently to this Authority in written form.

☒ furnished subsequently to this Authority in computer readable form.

☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/08743

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 2-35	YES
	Claims 1	NO
Inventive Step (IS)	Claims 2-35	YES
	Claims 1	NO
Industrial Applicability (IA)	Claims 1-35	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Claim 1 lacks novelty under PCT Article 33(2) as being anticipated by WO 98/46637.

WO 98/46637 discloses a method in which a cell is provided with viral vectors containing therapeutic genes and expression constructs encoding Us3 polypeptide and/or ICP4 polypeptide to protect the infected cells from virally induced apoptosis (see pages 34-38, particularly line 29 of page 34 continues to line 2 of page 35; page 37, lines 3-9).

The method taught by WO 98/46637 meets every limitation of the instant claim. Accordingly, claim 1 is anticipated by the reference.

None of the references WO 98/46637, US 6,207,648 and US 5,688,773 teaches or fairly suggests a method for prolonging expression of a heterologous gene in a cell infected with a vector encoding the heterologous gene, comprising infecting a cell with a vector encoding an apoptosis inhibiting agent, and wherein the heterologous gene encodes a prodrug activating enzyme.

Claims 2-35 met the criteria set out in PCT Article 33(2) and (3), because the prior art does not teach or fairly suggest the methods as claimed by the present application.

Claims 1-35 meet the criteria set out in PCT Article 33(4), because the prior art does not teach or fairly suggest the claimed invention.